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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,498

08/05/2003

Randall Woods

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

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3774

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/634,498	Applicant(s) WOODS ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-5-10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,33,35,38-54 and 56-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,33,35,38-54 and 56-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 32-33,35,36,38-54,56-69 have been considered but are not persuasive.

Applicant argues at page 10 of the Remarks that claim 53 was amended to recite “an optic disposed about an axis, the optic being biased to a dis-accommodated state”, and such amendment overcomes Horn. The optic is disclosed in Horn to stretch (or bias) to the un-accommodated state, and requires to ciliary muscle and/or zonule action to achieve the accommodated state. Thus the manner of implantation can be described as biasing the optic to the flatter or un-accommodated state.

With respect to claims 32 and 48 (Remarks page 11), Examiner repeats the above argument that the optic in Horn is biased to be flat as evidenced by Applicant at the bottom of Remarks page 11. The claims do not require how the lens/optic is biased to the unaccommodated state.

However in view of new claims 72-77, a new grounds of rejection is set forth below whereby Zadno-Azizi and Portney each teach it is well known in the art, and a matter of design choice to bias an IOL or optic of an IOL to the accommodated or unaccommodated state. Examiner maintains the current independent claims 32, 48, and 53 are met by the previously cited art, and do not require further teachings of obviousness by Zadno-Azizi or Portney although future amendments to include language of claims 72-77 (the IOL being biased to unaccommodated state, haptics

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being more rigid, etc.) would be obvious in view of Zadno-Azizi and/or Portney as set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53-54,58,59,66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn et al. USPN 4888012 (“Horn”).

Horn disclose in figures 4-6 an intraocular lens comprising arms 84 and legs 44, collectively forming the outer body of a positioning member surrounding optic lens 12. Accommodation is achieved via external forces causing a shape and curvature of the optic to change. The optic may be formed of gel or liquid material.

The lens is sized for use as claimed, as the overall diameter of one device is inherently capable of matching ciliary muscles of a certain patient or zonules of a patient having smaller eyes (a child or smaller animal, for example), and arms 84 are capable of moving inward whether by being pushed or relaxed (constriction of arms 84 still moves the material of the arm radially inward).

Regarding the new language “an optic disposed about an axis, the optic being biased to a dis-accommodated state”, the optic is disclosed in Horn to be stretched (or biased) to the un-accommodated state, and requires to ciliary muscle and/or zonule

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action to achieve the accommodated state. Thus the manner of implantation can be described as biasing the optic to the flatter or un-accommodated state. The claims do not require how the optic is biased in a manner different from Horn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32-33,35-36,38-52,56-57,60-65,69-72-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn et al. USPN 4888012 ("Horn") as applied to claims 53-55,58,59,66-68 above and in further view of Hanna USPN 6749634, Zadno-Azizi USPN 20030074060 ("Zadno-Azizi"), and Portney USPN 7097660.

Horn is described supra. With respect to claims 32, 44, 47, 48, 51, 52, 56, and 57, Horn is silent as to providing the optic between the planes, an opening anterior to the optic, an opening behind the optic, an annular portion anterior of the optic, and anterior/posterior segments located anteriorly/posteriorly of the optic. Hanna discloses an accommodating lens system for placement in the capsular bag wherein the outer body of the positioning member comprises anterior and posterior segments located anterior and posterior of the optic and comprises openings anterior and posterior of the optic such that the optic is between planes as claimed. The positioning member is shaped to conform to a capsular bag.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the positioning member of Horn to include anterior and posterior segments located anteriorly and posteriorly of the optic as taught in Hanna in order to provide the lens system with a configuration for placement in the capsular bag. Both devices are disclosed to accommodate in response to the natural eye muscle function and are considered analogous art.

Regarding claims 42,43 and 49, Hanna and Horn are silent as to the dimension along the optical axis and the diopter power of the lens. However, Hanna and Horn are directed to accommodating implants which are adapted to treat a wide range of patients. Therefore it would have been obvious to one of ordinary skill in the art to select the particular sizes and optical powers in order to fit a particular patients needs. Furthermore, the claimed ranges are well within ranges known in the art and would thus be a matter of obvious design choice.

Regarding claims 72-77, with respect to limitations regarding stiffer haptics or a pushing/compressive force, the lens of Horn is designed to be stretched to an unaccommodated state and then compressive forces from the ciliary body relax the haptics to cause accommodation. Since the lens haptics are tensioned in the unaccommodated state, it arguably does not provide a pushing or compressive force on the lens during accommodation (compression force from the ciliary muscles). Each of Portney and Zadno-Azizi teach accommodating IOLs wherein the at-rest state of the lens is unaccommodated and the haptics directly translate a compressive force to cause accommodation. Zadno-Azizi teach biasers 1000 (paragraph 0209 and figures 38C-D)

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which can provide a haptic with flexibility to bias a lens in either of the accommodated or unaccommodated state as needed for a particular patient. Portney teach in Figure 18 an accommodating IOL whereby the IOL is biased to an unaccommodated state and haptics are designed to be stiffer such that they translate the compressive force from the ciliary body to an optical lens to deform it. See column 2 lines 60-66, column 11, and figure 18. Thus the prior art show it is well known in the art to design accommodating IOLs wherein the IOL system is biased to the unaccommodated state and utilizes relatively stiff haptics to translate compressive forces. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the IOL of Horn in view of Hanna such that the optic and haptics are biased to an unaccommodated state and utilize relatively rigid haptic members to translate the compressive forces of the ciliary muscle to achieve accommodation as is well known in the art. It is further noted that applicant's specification does not suggest a particular benefit of biasing a IOL system to the accommodated or unaccommodated state (see current specification at page 20 lines 22-26 whereby Applicant acknowledges the equivalence between construction of unaccommodated and accommodated IOLs are admitted.) Even further, should applicant show that the limitations of claims 53-54,58,59, and 66-68 somehow overcome the purported anticipation in view of Horn's unaccommodated state, Examiner maintains claims 53-54,58,59,66-68 would alternatively be obvious in view of the teachings in Zadno-Azizi and Portney as set forth in this paragraph.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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